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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,817

04/08/2005

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P-5856

9959

7590

08/09/2007

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EXAMINER

SCHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,817	Applicant(s) ALHEIDT ET AL.	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Trenner (US Patent No. 4,781,684). Trenner discloses an IV flush syringe assembly (Figs. 1-14) comprising: a barrel (4) having an inside surface (30) including a recess (Fig. 4, recess is labeled as 32 and 36) and defining a chamber (76) for retaining fluid, an open proximal end (6) and a distal end (8) including a distal wall (wall at 8) with an elongated tip extending distally therefrom having a passageway therethrough (46) in fluid communication with said chamber; a plunger (2) including an elongated body portion (18) having a proximal end (22), a distal end (near 20) and a flexible stopper (Figs. 11-13, 100) slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber (col. 3, lines 35-40 disclose that the syringe is used for both aspiration and ejection of fluid) by movement of said stopper relative to said barrel, said stopper having an outwardly projecting rib (Fig. 11, rib is designated as 108 and 110) and said elongated body portion extending outwardly from said open proximal end of said barrel (Fig. 12, for example); wherein said recess receives said rib when said stopper is in contact with

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said distal wall (Fig. 13 discloses that the rib is received in the recess (32, 36) when the stopper is in contact with said distal wall) thereby holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Fig. 13).

In reference to claim 3, Trenner discloses that the rib (108, 110) is an annular rib (Figs. 11 and 14) and that the recess is an annular recess (Figs. 1-5).

In reference to claim 10, Trenner discloses a needle assembly (10) including a cannula (10) having a proximal end, a distal end and a lumen therethrough (Fig. 1), and a hub (44) having an open proximal end containing a cavity and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber (Figs. 1-3).

In reference to claim 11, Trenner discloses that the stopper is made from material selected from the group consisting of thermoplastic elastomers, natural rubber, synthetic rubber and combinations thereof (col. 7, lines 53-62).

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Trenner (US Patent No. 4,781,684). Trenner discloses an IV flush syringe assembly (Figs. 1-14) comprising: a barrel (4) having an inside surface (30) defining a chamber (76) for retaining fluid, an open proximal end (6) and a distal end (8) including a distal wall (wall at 8) with an elongate tip extending distally therefrom having a passageway

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therethrough (46) in fluid communication with said chamber, said inside surface further including a contact area (32, 36) at the distal end of said barrel, a plunger (2) including an elongate body portion (18) having a proximal end (22), a distal end (near 20) and a flexible stopper (Figs. 11-14, 100) slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber (col. 3, lines 35-40 disclose that the syringe is used for both aspiration and ejection of fluid) by movement of said stopper relative to said barrel, said elongated body portion extending outwardly from said open proximal end of said barrel (Fig. 12); wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for engaging said stopper when said stopper is in contact with said distal wall of said barrel for holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (clearly the recess (32, 36) creates a higher coefficient of friction which inherently helps prevent further movement of the plunger; Fig. 13 discloses that the rib is received in the recess (32, 36) when the stopper is in contact with said distal wall).

In reference to claim 21, Trenner discloses a needle assembly (10) including a cannula (10) having a proximal end, a distal end and a lumen therethrough (Fig. 1), and a hub (44) having an open proximal end containing a cavity and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber (Figs. 1-3).

In reference to claim 22, Trenner discloses that the stopper is made from material selected from the group consisting of thermoplastic elastomers, natural rubber, synthetic rubber and combinations thereof (col. 7, lines 53-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trenner (US Patent No. 4,781,684). Trenner discloses the device substantially as claimed including the contact area (32, 36) having an annular deformation (32 and 36 are a recess, i.e. an annular deformation). Trenner, however, does not disclose that there are a plurality of annular deformations. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include multiple annular deformations, since it has been held that mere duplication of the essential working parts

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of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 7-9 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trenner (US 4,781,684) in view of Lynn (US Patent No. 5,522,804). Trenner discloses the device substantially as claimed except for a tip cap and flush solution. Lynn, however, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), as better described by Col. 14, lines 20-30). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Trenner with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution, since the syringe of Palmer is structurally equivalent to a flushing syringe and is therefore perfectly capable of being used as a flushing syringe.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-11, 18-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons